

**PATENT**  
Attorney Docket No. **UM-08477**

**IN THE CLAIMS**

Claim 1 (currently amended): A method of treating or ameliorating a hyperproliferative disease in a subject comprising administering to said subject a therapeutically effective dose of a gossypol compound and one or more second agent(s) selected from an anticancer agent and/or radiation, wherein said gossypol compound is selected from the group consisting of ( $\pm$ )-ethyl gossypol, (-)-ethyl gossypol, (+)-ethyl gossypol, ~~( $\pm$ ) hemigossypolone~~, ~~(-)~~ hemigossypolone, ~~(+)~~ hemigossypolone, ( $\pm$ )-apogossypol, (-)-apogossypol, (+)-apogossypol, ( $\pm$ )-apogossypol acetic acid, (-)-apogossypol acetic acid, (+)-apogossypol acetic acid, ( $\pm$ )-ethyl apogossypol, (-)-ethyl apogossypol, and (+)-ethyl apogossypol.

Claim 2 (previously presented): The method of claim 1, wherein said gossypol compound is provided in a dose that sensitizes said subject to treatment by said one or more second agent(s).

Claims 3-26 (canceled)

Claim 27 (original): The method of claim 1, wherein said hyperproliferative disease is associated with overexpression of a Bcl-2 family member protein.

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Claim 28 (original): The method of claim 27, wherein said Bcl-2 family protein is Bcl-2, Bcl-X<sub>L</sub>, Mcl-1, A1/BFL-1, BOO-DIVA, Bcl-w, Bcl-6, Bcl-8, or Bcl-y.

Claim 29 (original): The method of claim 1, wherein said subject is a human.

Claim 30 (original): The method of claim 1, wherein said hyperproliferative disease is cancer.

Claim 31 (previously presented): The method of claim 30, wherein said cancer is breast cancer, prostate cancer, pancreatic cancer, colon cancer, lung cancer, leukemia, lymphoma, melanoma, or head-neck cancer.

Claim 32 (original): The method of claim 30, wherein said cancer is metastatic.

Claim 33 (original): The method of claim 30, wherein said cancer is a tumor and the treatment or amelioration results in regression of the tumor.

Claim 34 (previously presented): The method of claim 30, wherein said cancer is resistant to anticancer agent and/or radiation therapy.

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Claim 35 (previously presented): The method of claim 34, wherein said gossypol compound sensitizes said cancer to said anticancer agent and/or radiation therapy.

Claim 36 (previously presented): The method of claim 1, wherein said gossypol compound and said anticancer agent and/or radiation are administered simultaneously.

Claim 37 (previously presented): The method of claim 1, wherein said gossypol compound and said anticancer agent and/or radiation are administered sequentially.

Claim 38 (previously presented): The method of claim 37, wherein said gossypol compound is administered prior to said anticancer agent and/or radiation.

Claim 39 (previously presented): The method of claim 37, wherein said gossypol compound is administered after said anticancer agent and/or radiation.

Claim 40 (previously presented): The method of claim 1, wherein said gossypol compound and said anticancer agent and/or radiation are administered with different periodicities, different durations, different concentrations, and/or different administration routes.

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Claim 41 (previously presented): The method of claim 1, wherein said anticancer agent and/or radiation is selected from docetaxel, paclitaxel, cisplatin, carboplatin, radiation therapy, and combinations thereof.

Claim 42 (canceled)

Claim 43 (previously presented): The method of claim 1, wherein said gossypol compound and said anticancer agent and/or radiation have a synergistic therapeutic effect.

Claim 44 (original): The method of claim 1, wherein said disease is a neoplastic disease.

Claim 45 (original): The method of claim 1, wherein said second agent is radiation.

Claim 46 (currently amended): A pharmaceutical composition comprising a gossypol compound and one or more anticancer agents, wherein said gossypol compound is selected from the group consisting of ( $\pm$ )-ethyl gossypol, (-)-ethyl gossypol, (+)-ethyl gossypol, ( $\pm$ )~~hemigossypolone~~, ( $-$ )~~hemigossypolone~~, ( $+$ )~~hemigossypolone~~, ( $\pm$ )-apogossypol, (-)-apogossypol, (+)-apogossypol, ( $\pm$ )-apogossypol acetic acid, (-)-apogossypol acetic acid, (+)-apogossypol acetic acid, ( $\pm$ )-ethyl apogossypol, (-)-ethyl apogossypol, and (+)-ethyl apogossypol.

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Claim 47 (previously presented): The pharmaceutical composition of claim 46, wherein said anticancer agent is selected from docetaxel, paclitaxel, cisplatin, carboplatin, and combinations thereof.

Claim 48 (canceled)

Claim 49 (currently amended): A kit comprising a gossypol compound, one or more anticancer agents, and instructions for administering said gossypol compound and said anticancer agents to a subject, wherein said gossypol compound is selected from the group consisting of ( $\pm$ )-ethyl gossypol, (-)-ethyl gossypol, (+)-ethyl gossypol, ( $\pm$ )-~~hemigossypolone~~, ( $\rightarrow$ )-~~hemigossypolone~~, (+)-~~hemigossypolone~~, ( $\pm$ )-apogossypol, (-)-apogossypol, (+)-apogossypol, ( $\pm$ )-apogossypol acetic acid, (-)-apogossypol acetic acid, (+)-apogossypol acetic acid, ( $\pm$ )-ethyl apogossypol, (-)-ethyl apogossypol, and (+)-ethyl apogossypol.

Claim 50 (previously presented): The kit of claim 49, wherein said anticancer agent is selected from docetaxel, paclitaxel, cisplatin, carboplatin, and combinations thereof.

Claim 51 (canceled)

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Claim 52 (currently amended): A method of treating or ameliorating cancer a hyperproliferative disease in a subject comprising administering to said subject a therapeutically effective dose of a gossypol compound selected from ( $\pm$ )-gossypol, (-)-gossypol, ( $\pm$ )-gossypol acetic acid , and (-)-gossypol acetic acid and one or more second agent(s) selected from docetaxel, paclitaxel, ~~eisplatin~~, and/or radiation, wherein the combination of a gossypol compound and (a) second agent(s) produces a synergistic effect with respect to one or more of tumor shrinkage, tumor loss, time to tumor progression, or survival, with the proviso that a combination of ( $\pm$ )-gossypol, heat, and radiation is not administered.

Claim 53 (previously presented): The method of claim 52, wherein said gossypol compound is provided in a dose that sensitizes said subject to treatment by said one or more second agent(s).

Claim 54 (previously presented): The method of claim 52, wherein said gossypol compound is ( $\pm$ )-gossypol.

Claim 55 (previously presented): The method of claim 52, wherein said gossypol compound is (-)-gossypol.

Claims 56-59 (canceled)

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Claim 60 (previously presented): The method of claim 52, wherein said gossypol compound is ( $\pm$ )-gossypol acetic acid.

Claim 61 (previously presented): The method of claim 52, wherein said gossypol compound is (-)-gossypol acetic acid.

Claims 62-77 (canceled)

Claim 78 (currently amended): The method of claim 52, wherein said cancer ~~hyperproliferative disease~~ is associated with overexpression of a Bcl-2 family member protein.

Claim 79 (previously presented): The method of claim 78, wherein said Bcl-2 family protein is Bcl-2, Bcl-X<sub>L</sub>, Mcl-1, A1/BFL-1, BOO-DIVA, Bcl-w, Bcl-6, Bcl-8, or Bcl-y.

Claim 80 (previously presented): The method of claim 52, wherein said subject is a human.

Claim 81 (canceled)

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Claim 82 (currently amended):      The method of claim 52 84, wherein said cancer is breast cancer, prostate cancer, pancreatic cancer, colon cancer, lung cancer, leukemia, lymphoma, melanoma, or head-neck cancer.

Claim 83 (previously presented):      The method of claim 82, wherein said cancer is breast cancer or prostate cancer.

Claim 84 (currently amended):      The method of claim 52 84, wherein said cancer is metastatic.

Claim 85 (currently amended):      The method of claim 52 84, wherein said cancer is a tumor and the treatment or amelioration results in regression of the tumor.

Claim 86 (previously presented):      The method of claim 85, wherein the treatment or amelioration results in complete regression of the tumor.

Claim 87 (currently amended):      The method of claim 52 84, wherein said cancer is resistant to anticancer agent or radiation therapy.

Claim 88 (previously presented):      The method of claim 87, wherein said gossypol compound sensitizes said cancer to said anticancer agent(s) and/or radiation therapy.

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Claim 89 (previously presented): The method of claim 52, wherein said gossypol compound and said one or more second agent(s) are administered simultaneously.

Claim 90 (previously presented): The method of claim 52, wherein said gossypol compound and said one or more second agent(s) are administered sequentially.

Claim 91 (previously presented): The method of claim 90, wherein said gossypol compound is administered prior to said one or more second agent(s).

Claim 92 (previously presented): The method of claim 90, wherein said gossypol compound is administered after said one or more second agent(s).

Claim 93 (previously presented): The method of claim 52, wherein said gossypol compound and said one or more second agent(s) are administered with different periodicities, different durations, different concentrations, and/or different administration routes.

Claims 94-95 (canceled)

Claim 96 (previously presented): The method of claim 52, wherein said second agent is radiation.